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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,857	03/11/2004	James F. Brown	832_001 DIV3	7179
25191	7590	02/05/2008		
BURR & BROWN PO BOX 7068 SYRACUSE, NY 13261-7068			EXAMINER CHIN, CHRISTOPHER L	
			ART UNIT	PAPER NUMBER
			1641	
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			02/05/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/798,857

Applicant(s)

BROWN, JAMES F.

Examiner

Christopher L. Chin

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 and 58-146 is/are pending in the application.
- 4a) Of the above claim(s) 58-61 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-42 and 62-146 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-8 and 132-146, drawn to methods for detecting the presence of a single target nucleic acid molecule in a sample, classified in class 435, subclass 6.
 - II. Claims 9-42, 62-85, 103, 121, and 122 drawn to methods for detecting whether at least one molecule of a target nucleic acid is present in a first sample portion, classified in class 435, subclass 6.
 - III. Claims 86-102 and 123, drawn to a microfluidic device, classified in class 435, subclass 287.1.
 - IV. Claim 103, drawn to a method for detecting target nucleic acid using a porous sample structure, classified in class 436, subclass 518.
 - V. Claims 104-105, drawn to a microfluidic device with a porous sample structure, classified in class 422, subclass 50.
 - VI. Claims 106-107, drawn to a microfluidic assembly with 2 affinity regions, classified in class 422, subclass 57.
 - VII. Claim 108, drawn to a method for detecting target nucleic acid using a sample chamber with means for minimizing diffusion of sample, classified in class 436, subclass 514.

- VIII. Claim 109, drawn to a microfluidic device with a sample chamber having means for minimizing diffusion of sample, classified in class 422, subclass 58.
- IX. Claim 110, drawn to a method for quantifying a number of sample portions that contain target nucleic acid, classified in class 435, subclass 6.
- X. Claim 111, drawn to a method for determining a detectable concentration by quantifying numbers of peaks, classified in class 435, subclass 6.
- XI. Claim 112, drawn to a method for determining a detectable concentration by detecting an intensity of at least one peak, classified in class 435, subclass 6.
- XII. Claim 113, drawn to a method for detecting for each a plurality of sample portions whether the sample portions include at least one molecule of a target nucleic acid, classified in class 435, subclass 6.
- XIII. Claim 114, drawn to a microfluidic device with 2 sample retaining elements, classified in class 435, subclass 287.2.
- XIV. Claim 115, drawn to a method, classified in class 436, subclass 524.
- XV. Claim 116, drawn to a method of making a microfluidic device, classified in class 435, subclass 4.
- XVI. Claim 117, drawn to a microfluidic device with a sample retaining element that exhibits hydrophobicity, hydrophilicity, electromagnetic force exertion, or electrostatic force exertion, classified in class 422, subclass 55.

- XVII. Claim 118, drawn to a microfluidic device with a first element that has at least one hydrophilic pattern, classified in class 435, subclass 287.9.
- XVIII. Claim 119, drawn to a method using a device with a flow through channel and electrodes, classified in class 436, subclass 525.
- XIX. Claim 120, drawn to a method using a microfluidic device with plural sample chambers, classified in class 436, subclass 518.
- XX. Claim 124, drawn to a method for detecting a target nucleic acid using a device with a sample chamber that has a microcapillary device, classified in class 435, subclass 6.
- XXI. Claims 125-127, drawn to a microfluidic device/assembly with a sample chamber that has a microcapillary device, classified in class 435, subclass 288.4.
- XXII. Claim 128, drawn to a method of detecting a target nucleic acid that includes the use of a curable fluid, classified in class 436, subclass 501.
- XXIII. Claim 129, drawn to a method for detecting an amplification product, classified in class 435, subclass 6.
- XXIV. Claims 130-131, drawn to method for amplifying a nucleic acid, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I, II, IV, VII, IX-XII, XIV, XV, XVIII-XX, and XXII-XXIV are unrelated.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use

together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are unrelated because they are not disclosed as capable of use together and they have different designs, modes of operation, and effects as shown by the different steps, reagents, and devices used in each of the methods recited in Groups I, II, IV, VII, IX-XII, XIV, XV, XVIII-XX, and XXII-XXIV.

3. Inventions III, V, VI, VIII, XIII, XVI, XVII, and XXI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are unrelated because the devices in Groups III, V, VI, VIII, XIII, XVI, XVII, and XXI are not disclosed as capable of use together and they have different designs, modes of operation, and effects.

4. Inventions XV and III, V, VI, VIII, XIII, XVI, XVII, and XXI are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the process of Group XV is not for making any of the devices in Groups III, V, VI, VIII, XIII, XVI, XVII, and XXI.

5. Inventions (I, II, IV, VII, IX-XII, XIV, XVIII-XX, or XXII-XXIV) and (III, V, VI, VIII, XIII, XVI, XVII, or XXI) are related as processes and apparatus for their practice. The

inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus of Groups III, V, VI, VIII, XIII, XVI, XVII, and XXI as claimed can be used to practice another and materially different process such as any one of the methods of Groups I, II, IV, VII, IX-XII, XIV, XVIII-XX, or XXII-XXIV.

6. Claims 58-61 are being withdrawn from consideration at this time since they depend from cancelled claim 56.

7. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

8. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not

distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher L. Chin whose telephone number is (571) 272-0815. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Christopher L. Chin
Primary Examiner
Art Unit 1641

1/31/08